### Frequently Asked Questions

#### Laser Hair Removal

#### What is LHR?

LHR means Laser Hair Removal. Laser Hair Reduction is also an equivalent term.

#### What are Laser Hair Removal devices?

Laser Hair Removal devices are any lasers or IPL's used for removing hair.

#### Does §289.302 apply to Intense Pulse Light Devices (IPL)?

Yes, this rule applies to lasers or IPL's for the use of hair removal.

#### Are LHR devices required to be registered under §289.301?

LHR devices will need to be registered under the new rule §289.302 Registration and Radiation Safety Requirements for Use of Laser Hair Removal Devices. You will need to register your laser under §289.301 Registration and Radiation Safety Requirements for Lasers and Intense-Pulsed Light Devices if the lasers are used for any other purposes aside form laser hair removal.

#### Is there a time when we will need both certificates?

Yes, if the facility has a laser that performs LHR procedures and other procedures (for example photo facials, skin rejuvenation, etc.) then the facility will need to obtain a certificate under §289.301 and §289.302. The exception to this rule is if the facility is owned and/or operated by a physician for both the practice of medicine and LHR procedures, then they are exempt for obtaining a certificate of registration under §289.302.

#### Will other rules apply to laser users, like medical devices rules?

Yes, see Health and Safety Code 431, 25 TAC §229.431, §289.301 Registration and Radiation Safety Requirements for Lasers and Intense-Pulsed Light Devices, also §289.302 (b)(10) pertains to prescription devices and §289.302 (q)(2) concerns adulteration or misbranding of a LHR device.

Also see <u>Policy regarding Purchase</u>, <u>Possession</u>, and use of <u>Laser Hair Removal Devices</u>.

Is a prescription required for each laser hair removal procedure?

No, a prescription is not required for each LHR procedure. A written contract with the consulting physician that includes the protocols for the services provided at the facility will meet the requirements in regard to a prescription for each use. See <a href="Policy regarding Purchase">Policy regarding Purchase</a>, <a href="Possession">Possession</a>, and use of Laser Hair Removal Devices.

#### How were the fees established for the certification?

The fees are set to allow the department to collect 100% of the regulatory cost needed to run the program such as administrating the licensing, certification and inspection program.

#### Who can purchase and own a laser?

A physician's order or a prescription is required for the purchase of a LHR device. A LHR device may be owned by the facility and used by an individual who meets the requirements of §289.302.

See <u>Policy regarding Purchase</u>, <u>Possession</u>, and use of <u>Laser Hair Removal Devices</u>.

#### Can I purchase a LHR device from the internet?

The rules do not specify where to purchase a LHR device, however the device must be approved by the United States Food and Drug Administration and the purchase must be pursuant to an order by or prescription of a physician. To determine if your device is approved by the FDA please visit their website at <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm</a>

### I have a laser that is used for photo facials and hair removal do I have to register my device?

Yes, if a laser is used for procedures other than LHR and owned or operated by a physician for the practice of medicine, then the device is required to be registered under §289.301 Registration and Radiation Safety Requirements for Lasers and Intense Pulsed Light Devices. However, if the laser is not owned or operated by a physician for the practice of medicine then a registration is needed under §289.302 Registration and Radiation Safety Requirements for Use of Laser Hair Removal devices.

### What does the physician order have to include for the purchase of a laser hair removal device?

A prescription or other order shall include at a minimum the date the order is issued, the name and quantity of the LHR device (s) authorized to be purchased

and the name, address, and telephone number of the registered LHR facility authorized to purchase and own the laser.

The requirements for the physician purchase order can be found in  $\S 289.302$  (q)(2).

### Are facilities using devices purchased prior to the implementation of the §289.302 required to comply with §289.302.

Yes, the U.S. Food and Drug Administration has statutes concerning prescription devices effective prior to the implementation of House Bill 449 and §289.302.

#### Will my equipment be detained for the lack of prescription for each client?

No, the use of lasers only for hair removal is not for the practice of medicine therefore a prescription is not needed for every procedure provided that the facility and personnel comply with the requirements of §289.302.

#### Will the facility need a medical director?

No, however each facility will need to obtain a written contract with a consulting physician.

#### What is the role of the consulting physician?

A consulting physician is a physician who has a contract with a LHR facility. See §289.302(m) for the responsibilities of the consulting physician.

#### Does a Physician Assistant, who owns a med spa need to register the spa?

Yes, a separate LHR application shall be submitted for each LHR facility. Each application submitted to the agency shall designate a LSO, LHR Professional and include a copy of the contract with a consulting physician. However, there are a few exceptions such as a facility owned or operated by a physician for the practice of medicine, a licensed hospital or a clinic owned or operated by a licensed hospital. Also see §289.302(i).

#### Will each LHR location need to register?

A separate LHR application shall be submitted for each LHR facility. Multiple locations will need separate registrations.

However, there are a few exceptions such as a facility owned or operated by a physician for the practice of medicine, a licensed hospital or a clinic owned or operated by a licensed hospital. Also see §289.302(i).

#### May we use disposable eye shields on our clients?

Yes, provided that the protective eyewear meet the requirements set forth in §289.302(q)(11).

### Where can I obtain the forms to get a certificate of LHR registration for my office?

The documents will be available on the website once the program is implemented. Please check the Laser Hair Removal website periodically for further updates.

#### Who is a licensed health professional?

A licensed health professional is an individual licensed under Texas Occupations Code, Title 3. The use of LHR devices and performance of LHR procedures are determined by that individual's professional licensing board.

# Can Chiropractors be included as a type of physician to use laser hair removal devices?

No, laser hair removal devices do not fall within the scope of practice for a chiropractor as determined by the professional's licensing board. See Texas Occupations Code, Title 3.

#### Can a LHR Professional purchase, possess and use the LHR device?

A physician's order or prescription is required for the purchase of a LHR device. The LHR device can only be purchased by a licensed health professional for the facility. The written contract with the consulting physician will meet the requirements for supervision for the use of the LHR device. The protocols developed will satisfy the requirements for a prescription for each use. Also see <u>Policy regarding Purchase</u>, <u>Possession</u>, and use of <u>Laser Hair Removal Devices</u>.

# Does a licensed Facialist need to obtain an individual certificate to perform LHR procedures?

Yes, a person who performs LHR procedures will need to obtain am individual certificate issued by the agency. You may provide to the agency documentation that verifies the requirements were completed prior to September 1, 2010 for the individual certificate.

# I am a facialist and I work under a dermatologist, will I have to get certified to perform LHR procedures?

No, the physician has the authority to delegate tasks. You will not need to obtain an individual certificate unless you no longer work under these conditions.

# Physicians can delegate to staff yet registered nurses are not allowed to use lasers. Will this rule supersede the rules of another license board?

The Texas Board of Nursing Position Statement 115.9, Performance of Laser Therapy by RNs or LVNs, states that it is not within the scope of nursing practice to perform the delivery of laser energy on a patient as an independent nursing function. Nurses who elect to accept physician delegation must meet certain criteria specified in the position statement.

#### Who can operate a laser hair removal device?

A person wishing to perform LHR procedures must apply for and obtain a certificate issued by the agency.

There are four (4) levels of LHR personnel each requiring different levels of training. The personnel include an Apprentice-In-Training, LHR Technician, Senior LHR Technician, and LHR Professional.

#### What are the qualifications for an Apprentice-In-Training?

An applicant for a LHR Apprentice-In-Training shall have a total of 40 hours of training with at least 24 hours of training in LHR device safety, laser physics, skin typing, skin reactions, treatment protocols, burns, eye protection, emergencies, and post-treatment protocols.

See §289.302(j) (18) for a complete list of all requirements.

#### What are the qualifications for a LHR Technician?

An applicant for a LHR Technician shall meet all the requirements of an Apprentice-In- Training and have performed at least 100 LHR procedures within 12 months.

See §289.302(j)(14) for a complete list of all requirements.

#### What are the qualifications for a Senior Technician?

An applicant for a Senior LHR Technician shall meet all the requirements of a LHR Technician and have directly supervised at least 100 LHR procedures within 12 months.

See §289.302(j)(10) for a complete list of all requirements.

#### What are the qualifications for a Laser Hair Removal Professional?

An applicant for a LHR Professional shall meet all the requirements of a Senior LHR Technician and be certified by a certification entity approved by the agency. See §289.302(j)(6) for a complete list of all requirements.

#### How do I obtain an individual certificate to perform LHR procedures?

In order to obtain an individual certificate to perform LHR procedures, you will need to meet the requirements for one of the four levels of personnel and supply written documentation that you have completed training from one of the agency-accepted training programs. See §289.302 (j) for a complete list of requirements.

#### What is considered a procedure to satisfy the 100 procedures performed?

A procedure is each separate treatment with a client involving the removal of hair from one of the four body areas.

- 1) head and neck
- 2) upper extremities, to include hands, arms, armpits and shoulders
- 3) torso, to include front and back, pelvis region and buttocks
- 4) lower extremities, to include legs and feet See §289.302 (d)(20)

# <u>I have successfully completed training from a program located outside of the United States.</u> Will this satisfy the departments training requirements?

Possibly, the training information will be reviewed and approved on a case by case base.

#### When will I be able to submit my documentation to obtain my certificate?

Please check the Laser Hair Removal website periodically for further updates.

#### Will policy and procedures be available for public review?

Yes. Records kept by the agency regarding regulated facilities can be available for public review through open records.

#### How do I make an open records request?

Texas Government Code Chapter 552 gives you the right to access all records created, received or maintained by the agency with a few exceptions. All request must be made in writing and reasonably identify the records you are requesting.

#### What records are required to be maintained at our facility?

Some of the required documents you must maintain on site are as follows... a prescription order for the purchase of any lasers, your manufacturer User's Manual, a copy of the consulting physician contract, current laser devices inventory, copy of yearly inventory audit, training logs for all technicians, records of quarterly audits conducted by consulting physician, and written protocols to include procedures for safety and patient assessments.

See §289.302 Figure (nn)

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